



Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules (No. 2) 2024

I, Nicholas Henderson, as delegate of the Minister for Health and Aged Care, make the following rules.

Dated 14 October 2024

Nicholas Henderson
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name	1
2 Commencement.....	1
3 Authority	1
4 Schedules.....	1
Schedule 1—Amendments	2
<i>Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022</i>	2
<i>Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022</i>	2
<i>Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022</i>	2

1 Name

This instrument is the *Therapeutic Goods (Authorised Supply) Amendment (SAS Guidance) Rules (No. 2) 2024*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsections 19(7A), 32CM(7A) and 41HC(6) of the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Biologicals—Authorised Supply) Rules 2022

1 Section 4 (definition of SAS guidance)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024) published by the Therapeutic Goods Administration, as in force or existing on 1 October 2024.

Note: The SAS Guidance is published at www.tga.gov.au.

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

2 Section 4 (definition of SAS guidance)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024) published by the Therapeutic Goods Administration, as in force or existing on 1 October 2024.

Note: The SAS Guidance is published at www.tga.gov.au.

Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022

3 Section 4 (definition of SAS guidance)

Repeal the definition, substitute:

SAS Guidance means the document titled *Special Access Scheme (SAS): Guidance for health practitioners accessing unapproved therapeutic goods* (Version 3.0, October 2024) published by the Therapeutic Goods Administration, as in force or existing on 1 October 2024.

Note: The SAS Guidance is published at www.tga.gov.au.